Acellular Dermal Matrix in Immediate Expander/Implant Breast Reconstruction: A Multicenter Assessment of Risks and Benefits

Michael Sorkin, MD; Ji Qi, MS; Hyungjin M. Kim, ScD; Jennifer B. Hamill, MPH; Jeffrey H Kozlow, MD; Andrea L. Pusic, MD; Edwin G. Wilkins, MD

Disclosure/Financial Support: Supported by NCI grant 1R01CA152192. None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

INTRODUCTION: Acellular dermal matrix (ADM) has gained widespread acceptance in immediate expander/implant reconstruction, due to perceived benefits of improved aesthetic outcomes and superior tissue expansion dynamics. Although previous investigators have evaluated its risks, few studies have assessed the impact of ADM on other outcomes, including patient-report measures [1-3]. The objective of this study was to evaluate the effects of ADM use on complications, time to exchange, and patient-report outcomes (PRO) in immediate expander/implant reconstruction.

METHODS: The Mastectomy Reconstruction Outcomes Consortium (MROC) Study used a prospective cohort design to evaluate patients undergoing post-mastectomy reconstruction from 11 centers and 57 participating surgeons. The current analysis focused on women receiving immediate tissue expander reconstruction following mastectomies for cancer treatment or prophylaxis. Medical records and PRO data were collected preoperatively and at three months and one year postoperatively. The PRO measures included the BREAST-Q and Numeric Pain Rating Scale (NPRS). Bivariate analyses and mixed effect logistic regression models were used to assess the effects of ADM use on complication rates, time to expander/implant exchange, patient satisfaction with breasts, postoperative pain and other PROs.

RESULTS: A total of 1,107 patients were evaluated, including 546 (49.3%) with ADM and 561 (50.7%) without ADM. Controlling for demographic and clinical covariates, there were no statistically significant differences between the ADM and non-ADM cohorts in overall complication rates (19.9% vs. 18.3%, p=0.40), major wound infections (3.6% vs. 1.9%, p=0.12)[3] or reconstructive failures (2.2% vs 1.0%, p=0.59) at one year following reconstruction. There were also no significant differences between the cohorts in the time to expander/implant exchange (p=0.89) or in one year post-operative PRO scores, including satisfaction with breast (p=0.14), psychosocial well-being (p=0.40), physical well-being (p=0.93) and postoperative pain (p=0.29).

CONCLUSION: In our multicenter, prospective analysis, we found no significant ADM effects on complications in immediate expander/implant breast reconstruction. Our analyses also noted no statistically significant differences between ADM and non-ADM cohorts for other outcomes, including time to exchange and PROs. The results of this study call into question the utility and value of ADM in immediate expander/implant reconstruction and suggest a need for further critical reassessment of ADM use in this setting.

REFERENCES:

1. Kim, J.Y., et al., *A meta-analysis of human acellular dermis and submuscular tissue expander breast reconstruction.* Plast Reconstr Surg, 2012. **129**(1): p. 28-41.
2. Lee, K.T. and G.H. Mun, *Updated Evidence of Acellular Dermal Matrix Use for Implant-Based Breast Reconstruction: A Meta-analysis.* Ann Surg Oncol, 2015.
3. Potter, S., et al., *Systematic review and critical appraisal of the impact of acellular dermal matrix use on the outcomes of implant-based breast reconstruction.* Br J Surg, 2015. **102**(9): p. 1010-25.